



The Japan Federation of Medical Devices Associations (JFMDA)

> 19 Associations

CT/MRI, Intervention, CRM,CV, Neuro, Ophthalmology, Anesthesia, IV Diagnostics, regenerative medicine and others

- ➤ 4900 Companies
- ➤ Sales revenue of ¥ 2,300B = \$23B representing 90% of the industry in Japan
- \triangleright Overseas sales >¥1,300B \rightleftharpoons \$13B
- **▶** 120K Jobs



Non Invasive diagnostic imaging

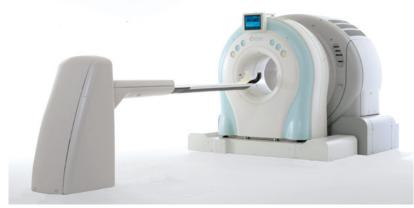
- ➤ Early detection of cancer cells and vascular disease with high definition imaging
- > Better for patients due to less exposure to radiation

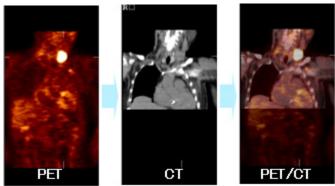
Multi-detector computed tomography



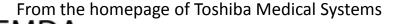


PET CT

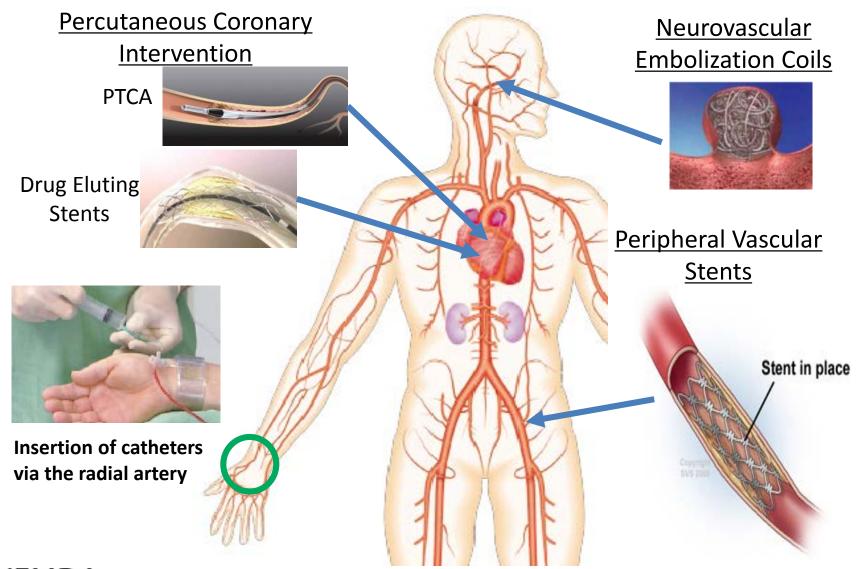




肺がん術後(左肺切除)後のリンパ節転移 From the homepage of Shimadzu



Interventional Neuroradiology, Cardiology, Peripheral Radiology





Investment in Brazil

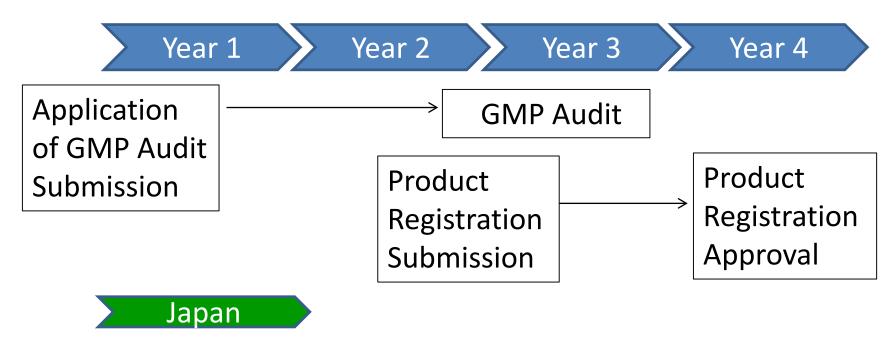
- TOSHIBA MEDICAL DO BRASIL LTDA.
 - New factory opened in 2013. (Sao Pauro).
 - Product: CT and Ultrasonograph
- HORIBA INSTRUMENTS BRASIL LTDA.
 - Factory opened in 2014 for reagent production (Sao Pauro) with US\$7M investment.
 - Employee: 70
 - Expected Sales: US\$40M in 2015



Ultrasonograph

Regulatory Issue

- GMP=BPF (Boas Praticas de Fabricacao) audit for the manufacturing sites outside the country
- Product registration for medical devices





Regulatory Issue

Proposals:

- Regular meeting
 - (1) ANVISA and PMDA
 - (2) ANVISA and Medical Device Committee at Câmara de Comércio e Indústria Japonesa do Brasil
- Collaboration with Japanese Stakeholders Visit Japan, and see how Japanese government or PMDA manages regulatory procedures, and also see QMS at medical device manufacturers



		Brasil	Japan
Average life expectancy (yrs)	1	74	83
Infant mortality rate (/1,000)		13	2
Cause of death	1	Cardiac disease	Cancer
	2	Cerebrovascular disease	Cardiac disease
	3	Cancer	Cerebrovascular disease

WHO World Health Statistics 2013



To contribute to healthcare and people of Brasil



Thank you

